K132942



**510(k) Summary**
**21 CFR 807.92**

## Site~Rite Vision* II Ultrasound System

| | | |
|---|---|---|
| **General Provisions** | Submitter Name:<br>Submitter Address: | Bard Access Systems, Inc.<br>605 North 5600 West<br>Salt Lake City, UT 84116 |
| | Contact Person: | Kerrie Hamblin<br>Senior Regulatory Affairs Specialist<br>Bard Access Systems, Inc.<br>kerrie.hamblin@crbard.com<br>801.522.5000 ext 4909<br>801.522.5425 fax |
| | Date of Preparation: | 18 September 2013 |
| **Subject Device** | Trade Name: | **Site~Rite Vision* II Ultrasound System** |
| | Classification Name: | IYN 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System<br>IYO 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System<br>ITX 21 CFR 892.1570 Diagnostic Ultrasonic Transducer<br>LLZ 21 CFR 892.2050 Picture Archiving and Communications System<br>Class II, Radiology |
| | Common Name: | IYN 21 CFR 892.1550 System, imaging, pulsed doppler, ultrasonic<br>IYO 21 CFR 892.1560 System, imaging, pulsed echo, ultrasonic<br>ITX 21 CFR 892.1570 Transducer, ultrasonic, diagnostic<br>LLZ 21 CFR 892.2050 System, image processing, radiological |
| **Predicate Devices** | Trade Name: | Site~Rite Vision* Ultrasound System |
| | Classification Name: | IYN 21 CFR 892.1550, Ultrasonic Pulsed Doppler Imaging System<br>IYO 21 CFR 892.1560, Ultrasonic Pulsed Echo Imaging System<br>ITX 21 CFR 892.1570, Diagnostic Ultrasonic Transducers<br>LLZ 21 CFR 892.2050, Picture Archiving and Communications System |
| | Common Name: | IYN 21 CFR 892.1550 System, imaging, pulsed doppler, ultrasonic<br>IYO 21 CFR 892.1560 System, imaging, pulsed echo, ultrasonic |

OCT 17 2013

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|---|---|
| | ITX 21 CFR 892.1570 Transducer, ultrasonic, diagnostic<br>LLZ 21 CFR 892.2050 System, image processing, radiological |
| Premarket Notification: | K100402, concurrence date 05 March 2010 |
| Manufacturer: | Bard Access Systems, Inc. |

**Device Description - Site~Rite Vision* II Ultrasound System**

The **Site~Rite Vision* II Ultrasound System** is a mobile device that features real-time 2D ultrasound imaging, color-flow Doppler, procedural recordings (cine), patient-information storage, image annotations, and various measurement and calculation tools. The typical environment for ultrasound imaging may include hospitals, outpatient clinics, and long-term care facilities.

**Indications for Use / Intended Use - Site~Rite Vision * II Ultrasound System**

The **Site~Rite Vision* II Ultrasound System** is intended for diagnostic ultrasound imaging or fluid-flow analysis of the human body. Specific clinical applications include:

- Fetal
- Abdominal
- Intra-operative (semi-critical†)
- Pediatric
- Peripheral Vessel
- Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)
- Musculo-skeletal (conventional and superficial)
- Cardiac (adult and pediatric)

Typical examinations performed using the **Site~Rite Vision* II Ultrasound System** include:

| Imaging Applications | Exam Type (adult & pediatric) |
|---|---|
| **Vascular** | Assessment of carotid arteries, aorta, deep veins, superficial veins in the arms and legs, select small vessels supporting organs |
| **Vascular Access** | Guidance for a PICC, CVC, dialysis catheter, port, PIV, and arterial-line placement, and peripheral vein and artery access |
| **Abdominal** | Assessment of liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, appendix, and surrounding anatomical structures |
| **Interventional and Intraoperative** | Guidance for biopsy, drainage, peripheral nerve blocks, and intraoperative procedures (semi-critical†) |
| **Superficial** | Assessment of breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal procedures, soft tissue structures, and surrounding anatomical structures |

† Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

| | |
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| **Technological Characteristics** | This device operates identically to the predicate device in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D images. Doppler shift caused by blood flow is displayed as color flow or spectrum analysis. The modes of this device (2D, color Doppler) are the same as the predicate device identified above. |

**Safety & Performance Tests**

Verification and validation activities were designed and performed to demonstrate that the subject **Site~Rite Vision* II Ultrasound System** met predetermined performance requirements. The following standards in conjunction with internal protocols were used to determine appropriate methods for evaluating the performance of the device:

| | |
|---|---|
| IEC 60601-1:2005, CORR. 1(2006), CORR 2(2007), AM1(2012), ANSI/AAM ES 60601/A2:2012, CAN/CSA-C22.2 | Medical Electrical Equipment - Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance – Edition 3.1 |
| IEC 60601-1-2:2007 | Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests |
| IEC 60601-2-37:2007 | Medical Electrical Equipment – Part 2-37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment |
| IEC 60601-1-6:2012 | Medical Electrical Equipment-Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability |
| NEMA UD 2:2004 | Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3 |
| NEMA UD 3:2004 | Standard for the Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2 |

| | | |
|---|---|---|
| | IEC 62304:2006 | Medical device software – Software life cycle processes – Edition 1.0 |
| | ISO 10993-1:2009 | Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process |
| | NEMA PS 3.1 – 3.18:2008 | Digital Imaging and Communications in Medicine (DICOM) Set |

The subject devices met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.

**Summary of Substantial Equivalence**

Based on the indications for use, technological characteristics, and safety and performance testing, the subject **Site~Rite Vision* II Ultrasound System** met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate device, Site~Rite Vision* Ultrasound System. Based on the performance testing, the **Site~Rite Vision* II Ultrasound System** is as safe, as effective, and performs as well as, or better than the predicate, Site~Rite Vision* Ultrasound System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 17, 2013

KERRIE HAMBLIN
C.R. BARD, INC.
605 NORTH 5600 WEST
SALT LAKE CITY UT 84116

Re: K132942
Trade/Device Name: Site~Rite Vision II Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN
Dated: September 18, 2013
Received: September 19, 2013

Dear Ms. Hamblin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Site~Rite Vision II Ultrasound System, as described in your premarket notification:

Transducer Model Number

60 mm ROC Convex  40 mm Linear  20 mm Linear

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

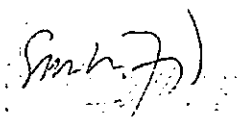
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

**Indications for Use Statement**

510(k) Number (if known): K132942

Device Name: **Site~Rite Vision* II Ultrasound System**

Indications for Use:

The **Site~Rite Vision* II Ultrasound System** is intended for diagnostic ultrasound imaging or fluid-flow analysis of the human body. Specific clinical applications include:

- Fetal
- Abdominal
- Intra-operative (semi-critical†)
- Pediatric
- Peripheral Vessel
- Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary)
- Musculo-skeletal (conventional and superficial)
- Cardiac (adult and pediatric)

Typical examinations performed using the **Site~Rite Vision* II Ultrasound System** include:

| **Imaging Applications** | **Exam Type (adult & pediatric)** |
|---|---|
| **Vascular** | Assessment of carotid arteries, aorta, deep veins, superficial veins in the arms and legs, select small vessels supporting organs |
| **Vascular Access** | Guidance for a PICC, CVC, dialysis catheter, port, PIV, and arterial-line placement, and peripheral vein and artery access |
| **Abdominal** | Assessment of liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, appendix, and surrounding anatomical structures |
| **Interventional and Intraoperative** | Guidance for biopsy, drainage, peripheral nerve blocks, and intraoperative procedures (semi-critical†) |
| **Superficial** | Assessment of breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal procedures, soft tissue structures, and surrounding anatomical structures |

† Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K132942
Page 1 of 1

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## Diagnostic Ultrasound Indications for Use
## (1 of 4)

TABLE 1.3-1
Ultrasound System: Site~Rite Vision* II Ultrasound System

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track 1 Only) | Specific (Tracks 1 and 3) | B | M | PWD | CWD | Color Doppler | Combined (B + CD) | Other* (specify) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging and Other | Fetal | P | | | | | P | |
| | Abdominal | P | | | | | P | |
| | Intra-operative (semi critical†) | P | | | | | P | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | | | | | P | |
| | Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary) | P | | | | | P | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card) | | | | | | | |
| | Musculo-skeletal (Conventional) | P | | | | | P | |
| | Musculo-skeletal (Superficial) | P | | | | | P | |
| | Intravascular | | | | | | | |
| | Other (specify) | | | | | | | |
| Cardiac | Cardiac Adult | P | | | | | P | |
| | Cardiac Pediatric | P | | | | | P | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (specify) | | | | | | | |
| Peripheral Vessel | Peripheral Vessel | P | | | | | P | |
| | Other (specify) | | | | | | | |

N=new indication; P=previously cleared by the FDA; E=added under this appendix
*Examples of other modes of operation may include: A mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging
† Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

Prescription use per 21 CFR 801.109

## Diagnostic Ultrasound Indications for Use
(2 of 4)

**TABLE 1.3-2**
**Ultrasound System: Site~Rite Vision* II Ultrasound System**
**Transducer: 60mm ROC convex Probe (128 element)**

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track 1 Only) | Specific (Tracks 1 and 3) | B | M | PWD | CWD | Color Doppler | Combined (B+CD) | Other* (specify) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging and Other | Fetal | P | | | | | P | |
| | Abdominal | P | | | | | P | |
| | Intra-operative (semi-critical†) | P | | | | | P | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | | | | | P | |
| | Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary) | | | | | | | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card) | | | | | | | |
| | Musculo-skeletal (Conventional) | P | | | | | P | |
| | Musculo-skeletal (Superficial) | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (specify) | | | | | | | |
| Cardiac | Cardiac Adult | P | | | | | P | |
| | Cardiac Pediatric | P | | | | | P | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (specify) | | | | | | | |
| Peripheral Vessel | Peripheral Vessel | P | | | | | P | |
| | Other (specify) | | | | | | | |

N=new indication; P=previously cleared by the FDA; E=added under this appendix
*Examples of other modes of operation may include: A mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging
†Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

Prescription use per 21 CFR 801.109

## Diagnostic Ultrasound Indications for Use
(3 of 4)

TABLE 1.3-3
Ultrasound System: Site~Rite Vision* II Ultrasound System
Transducer: 40mm Linear Probe (128 element)

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track 1 Only) | Specific (Tracks 1 and 3) | B | M | PWD | CWD | Color Doppler | Combined (B+CD) | Other* (specify) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging and Other | Fetal | P | | | | | P | |
| | Abdominal | P | | | | | P | |
| | Intra-operative (semi-critical†) | P | | | | | P | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | | | | | P | |
| | Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary) | P | | | | | P | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card) | | | | | | | |
| | Musculo-skeletal (Conventional) | P | | | | | P | |
| | Musculo-skeletal (Superficial) | P | | | | | P | |
| | Intravascular | | | | | | | |
| | Other (specify) | | | | | | | |
| Cardiac | Cardiac Adult | P | | | | | P | |
| | Cardiac Pediatric | P | | | | | P | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (specify) | | | | | | | |
| Peripheral Vessel | Peripheral Vessel | P | | | | | P | |
| | Other (specify) | | | | | | | |

N=new indication; P=previously cleared by the FDA; E=added under this appendix
*Examples of other modes of operation may include: A mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging
†Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

Prescription use per 21 CFR 801.109

## Diagnostic Ultrasound Indications for Use
(4 of 4)

TABLE 1.3-4
Ultrasound System: Site~Rite Vision* II Ultrasound System
Transducer: 20 mm Linear Probe (64 elements)

| Clinical Application | | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General (Track 1 Only) | Specific (Tracks 1 and 3) | B | M | PWD | CWD | Color Doppler | Combined (B+CD) | Other* (specify) |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging and Other | Fetal | P | | | | | P | |
| | Abdominal | P | | | | | P | |
| | Intra-operative (semi-critical†) | P | | | | | P | |
| | Intra-operative (Neuro) | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | P | | | | | P | |
| | Small Organ (breast, thyroid, parathyroid, testicles, prostate, uterus, ovary) | P | | | | | P | |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph. (non-Card) | | | | | | | |
| | Musculo-skeletal (Conventional) | P | | | | | P | |
| | Musculo-skeletal (Superficial) | P | | | | | P | |
| | Intravascular | | | | | | | |
| | Other (specify) | | | | | | | |
| Cardiac | Cardiac Adult | P | | | | | P | |
| | Cardiac Pediatric | P | | | | | P | |
| | Intravascular (Cardiac) | | | | | | | |
| | Trans-esoph. (Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (specify) | | | | | | | |
| Peripheral Vessel | Peripheral Vessel | P | | | | | P | |
| | Other (specify) | | | | | | | |

N=new indication; P=previously cleared by the FDA; E=added under this appendix
*Examples of other modes of operation may include: A mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging
†Semi-critical is defined as clinical applications in which the probe contacts mucous membranes or non-intact skin.

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription use per 21 CFR 801.109